## What is claimed is:

An implantable medical device system comprising:
 a sensor that is implantable within the body of a patient to sense electrical

cardiac activity and provide an indication of T-wave alternans within the heart of the patient; and

a T-wave analyzer, responsive to the sensor, that evaluates cardiac risk based on comparison of the indication of T-wave alternans to a predetermined criterion.

2. The system of claim 1, further comprising a pacing generator that applies increased rate pacing stimuli to the heart to facilitate sensing of the T-wave alternans by the sensor.

3. The system of claim 1, further comprising a second sensor that senses a state of increased heart rate by the patient, wherein the T-wave analyzer is responsive to the second sensor in the evaluation of cardiac risk.

4. The system of claim 1, further comprising a memory that stores the T-wave alternans indication provided by the sensor.

5. The system of claim 1, further comprising a device that provides an alert in the event the indication of T-wave alternans satisfies the predetermined criterion.

6. The system of claim 1, wherein the T-wave analyzer analyzes differences in the QT interval over a series of two or more heartbeats to evaluate the cardiac risk.

10

15

20

25

20

25



- 7. The system of claim 1, wherein the T-wave analyzer analyzes differences in the amplitude of the T-wave over a series of two or more heartbeats to evaluate the cardiac risk.
- 5 8. The system of claim 1, wherein the T-wave analyzer analyzes differences in the slope of the T-wave over a series of two or more heartbeats to evaluate the cardiac risk.
- 9. The system of claim 1, wherein the T-wave analyzer analyzes
  10 differences in T-wave characteristics over a series of two or more
  heartbeats to evaluate the cardiac risk.
  - 10. The system of claim 9, wherein the T-wave analyzer applies a Fourier analysis to at least a portion of the T-wave over a series of two or more heartbeats and cardiac risk based on differences in the Fourier analysis over the series of two or more heartbeats.
  - 11. The system of claim 9, wherein the T-wave analyzer compares alternate repolarization signals over a series of two or more heartbeats to evaluate the cardiac risk.
  - 12. The system of claim 9, wherein the T-wave analyzer counts the number of times the T-wave alternans satisfies the criterion, and indicates cardiac risk in the event the number exceeds a predetermined threshold.
  - The system of claim 1, further comprising a memory, wherein the T-wave analyzer analyzes a relationship between the T-wave alternans and the predetermined criterion over a period of time, and stores results of the analysis in the memory for access by a physician.
  - 14. The system of claim 1, wherein the T-wave analyzer includes a digital signal processor (DSP) that analyzes T-wave morphology as a basis for the evaluation of cardiac risk.

10

15

20

25

- 15. The system of claim 1, further comprising a pacing generator applies pacing stimuli to the heart to facilitate sensing of the T-wave alternans by the sensor, the system further comprising a processor that controls the pacing generator based on the indication of T-wave alternans to reduce cardiac risk for the patient.
- 16. A method for analyzing cardiac electrical activity, the method comprising:

sensing electrical cardiac activity using a sensor that is implanted within the body of a patient to provide an indication of T-wave alternans within the heart of the patient; and

evaluating card/ac risk based on comparison of the indication of Twave alternans to a predetermined criterion.

- 17. The method of claim 16, further comprising applying increased rate pacing stimuli to the heart using a pacing generator forming part of a device implanted within the body of the patient to facilitate sensing of the T-wave alternans by the sensor.
- 18. The method of claim 16, further comprising sensing a state of increased heart rate by the patient, and comparing the indication of T-wave alternans to the predetermined criterion in the event the state of increased heart rate is sensed.
- 19. The method of claim 16, further comprising storing the T-wave alternans indication provided by the sensor in a memory associated with a device implanted within the body of the patient.
- 20. The device of claim 16, further comprising providing an alert in the event the indication of T-wave alternans satisfies the predetermined criterion.

Inventor: John F. Norris et al.

- 21. The method of claim 16, further comprising analyzing differences in the QT interval over a series of two or more heartbeats to evaluate the cardiac risk.
- 5 22. The method of claim 16, further comprising analyzing differences in the amplitude of the T-wave over a series of two or more heartbeats to evaluate the cardiac risk.
- 23. The method of ¢laim 16, further comprising analyzing differences in the slope of the T-wave over a series of two or more heartbeats to evaluate 10 the cardiac risk.
  - 24. The method  $\phi$ f claim 16, further comprising analyzing differences in T-wave characterisfics over a series of two or more heartbeats to evaluate the cardiac risk.
- The method of claim 24, further comprising applying a Fourier 25. analysis to at least a portion of the T-wave over a series of two or more heartbeats and providing the indication of T-wave alternans based on differences in the Fourier analysis over the series of two or more 20 heartbeats.
- The method of claim 24, further comprising comparing alternate 26. repolarization signals over a series of two or more heartbeats to evaluate 25 the cardia¢ risk.
  - 27. The method of claim 24, further comprising counting the number of times the T-wave alternans satisfies the criterion, and generating an indication of cardiac risk in the event the number exceeds a predetermined threshold.
  - 28. The method of claim 16, further comprising analyzing a relationship between the T-wave alternans and the predetermined criterion over a

15

20

25

period of time, and storing results of the analysis in a memory associated with a device implanted within the patient for access by a physician.

- 29. The method of claim 16, further comprising analyzing T-wave morphology using a digital signal processor (DSP) associated with a device implanted within the patient as a basis for the indication of the T-wave alternans.
- 30. The method of claim 16, further comprising applying pacing stimuli to the heart to facilitate sensing of the T-wave alternans by the sensor, and controlling the pacing stimuli based on the indication of T-wave alternans to reduce cardiac risk for the patient.
  - 31. An implantable cardiac pacemaker device comprising:
    a pacing generator that generates electrical pacing stimuli;
    one or more leads, coupled to the pacing generator, that apply the
    electrical pacing stimuli to the heart of a patient;

a sensor that senses electrical cardiac activity and provides an indication of T-wave alternans within the heart of the patient; and

a T-wave analyzer, responsive to the sensor, that controls the pacing generator to generate increased rate electrical pacing stimuli to facilitate the sensing of the electrical cardiac activity by the sensor, and evaluates cardiac risk based on comparison of the indication of T-wave alternans to a predetermined criterion.

- 32. The device of claim 31, further comprising a memory that stores the T-wave alternans indication provided by the sensor.
- 33. The device of claim 31, further comprising a device that provides an alert in the event the indication of T-wave alternans satisfies the predetermined criterion.

20

25

- 34. The device of claim 31, wherein the T-wave analyzer analyzes differences in the QT interval over a series of two or more heartbeats to evaluate the cardiac risk.
- 5 35. The device of claim 31, wherein the T-wave analyzer analyzes differences in the amplitude of the T-wave over a series of two or more heartbeats to evaluate the cardiac risk.
- 36. The device of claim 31, wherein the T-wave analyzer analyzes differences in the slope of the T-wave over a series of two or more heartbeats to evaluate the cardiac risk.
  - 37. The device of claim 31, wherein the T-wave analyzer analyzes differences in T-wave characteristics over a series of two or more heartbeats to evaluate the cardiac risk.
  - 38. The device of claim 31, wherein the T-wave analyzer applies a Fourier analysis to at least a portion of the T-wave over a series of two or more heartbeats and evaluates cardiac risk based on differences in the Fourier analysis over the series of two or more heartbeats.
  - 39. The device of claim 38, wherein the T-wave analyzer compares alternate repolarization signals over a series of two or more heartbeats to evaluate the cardiac risk.
  - 40. The device of claim 38, wherein the T-wave analyzer counts the number of times the T-wave alternans satisfies the criterion, and generates an indication of cardiac risk in the event the number exceeds a predetermined threshold.
  - 41. The device of claim 38, further comprising a memory, wherein the T-wave analyzer analyzes a relationship between the T-wave alternans and

15

20

the predetermined criterion over a period of time, and stores results of the analysis in the memory for access by a physician.

- 42. The device of claim 38, wherein the T-wave analyzer includes a digital signal processor (DSP) that analyzes T-wave morphology as a basis for the evaluation of cardiac fisk..
  - 43. The device of claim \$1, further comprising a pacing generator that applies pacing stimuli to the heart to facilitate sensing of the T-wave alternans by the sensor, and a controller that controls the pacing generator based on the indication of cardiac risk to reduce cardiac risk for the patient.
  - 44. An implantable medical device system comprising:
    means, implantable within the body of a patient, for sensing electrical
  - cardiac activity and providing an indication of T-wave alternans within the heart of the patient; and

means, responsive to the sensing means, for evaluating cardiac risk based on comparision of the indication of T-wave alternans to a predetermined criterion.

- 45. The system of claim 44, further comprising means for applying increased rate pacing stimuli to the heart to facilitate sensing of the T-wave alternans by the sensing means.
- 25 46. The system of claim 44, further comprising means for sensing a state of increased heart rate by the patient, wherein the evaluating means is responsive to the state sensing means in evaluating cardiac risk.
- 47. The system of claim 44, further comprising means for storing the T30 wave alternans indication provided by the sensing means.

20

25

- 48. The system of claim 44, further comprising means for providing an alert in the event the indication of T-wave alternans satisfies the predetermined criterion.
- 5 49. The system of claim 44, wherein the evaluating means analyzes differences in the QT interval over a series of two or more heartbeats to evaluate the cardiac risk.
- 50. The system of claim 44, wherein the evaluating means analyzes differences in the amplitude of the T-wave over a series of two or more heartbeats to evaluate the cardiac risk.
  - 51. The system of claim 44, wherein the evaluating means analyzes differences in the slope of the T-wave over a series of two or more heartbeats to evaluate the cardiac risk.
  - 52. The system of claim 44, wherein the evaluating means analyzes differences in T-wave characteristics over a series of two or more heartbeats to evaluate the cardiac risk.
  - 53. The system of claim 52, wherein the evaluating means applies a Fourier analysis to at least a portion of the T-wave over a series of two or more heartbeats and provides the evaluation of cardiac risk based on differences in the Fourier analysis over the series of two or more heartbeats.
  - 54. The system of claim 52, wherein the evaluating means compares alternate repolarization signals over a series of two or more heartbeats to evaluate the cardiac risk.
  - 55. The system of claim 52, wherein the evaluating means counts the number of times the T-wave alternans satisfies the criterion, and generates

IMPLANTABLE MEDIO EVICE AND METHOD USING INTEGRATED T-WAVE ALTERNANS ANALYZER Attorney's Docket No. P-8873 Inventor: John F. Norris et al.

an indication of cardiac risk in the event the number exceeds a predetermined threshold.

- 56. The system of claim 44, further comprising a memory, wherein the evaluatingmeans analyzes a relationship between the T-wave alternans and the predetermined criterion over a period of time, and stores results of the analysis in the memory for access by a physician.
- 57. The system of claim 44, wherein the evaluatingmeans includes a digital signal processor (DSP) that analyzes T-wave morphology as a basis for the evaluation of cardiac risk.
  - 58. The system of claim 44, further comprising means for applying pacing stimuli to the heart to facilitate sensing of the T-wave alternans by the sensing means, the system further comprising a means for controlling the pacing generator based on the indication of T-wave alternans to reduce cardiac fisk for the patient.